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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Vitus Maria Huber

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

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06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,852	Applicant(s) HUBER ET AL.	
	Examiner Kristen C. Matter	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 2,6-14,16,18,19,32,33 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3-5,15,17,20-31,34-46 and 48-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/25/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1, 3-5, 13, 15, 17, 20-31, 34-46, and 48-51 in the reply filed on 4/23/2007 is acknowledged.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

In the present case, "37 CFR 1.56(a)" should be change to --37 CFR 1.56--.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

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- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Examiner strongly recommends that Applicant use appropriate headers in this application.

The disclosure is objected to because of the following informalities:

Claim numbers should not be referred to in the text. Examiner suggests deleting lines 14-16 on page 1 and lines 10-14 on page 3 to correct this problem.

Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tension element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "70" and "7" (page 14) have both been used to designate the hinge ring.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "20" has been used to designate multiple arrows in Figure 7.

The drawings are objected to because numerals are preferred to letters (i.e., F1, F2, F3).

The drawings are objected to because many of the reference characters are illegible in the Figures. Cleaned up lines and reference characters are required for full comprehension of the drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 13 is objected to because it is dependent on a withdrawn claim. Claim 13 should therefore also be withdrawn and accordingly has not been further treated on the merits.

Claims 26 and 27 are objected to because of the following informalities: reference characters referred to in the claims should be enclosed in parentheses. Appropriate correction is required.

Claim 42 is objected to because of the following informalities: on line 2, an angle α , β " should be changed to --angles α and β -- for plurality agreement. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 25, 36, 39, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 22, it is unclear what is meant by "similar to that of a ball joint". What aspects of the ball joint should be similar to the ends near the hinge?

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex*

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parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 25 recites the broad recitation "manufactured from metal or plastic", and the claim also recites "in particular from thin, carbon-fibre reinforced plate" which is the narrower statement of the range/limitation. Claim 39 recites the broad recitation "operate together with a step", and the claim also recites "in particular an annular step" which is the narrower statement of the range/limitation. Claim 48 recites the broad recitation "manufactured from plastic", and the claim also recites "in particular a plastic resistant to impact and not irritating to the skin, e.g., of the polycarbonate class" which is the narrower statement of the range/limitation.

Claim 36 recites the limitation "the edge regions" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "the hinge disk engaging elements" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 15, 17, 20, 21, 23-26, 29-31, 37, 49, and 51 are rejected under 35

U.S.C. 102(b) as being anticipated by Wilms (US 1, 213, 786).

Regarding claims 1, 3-5, 15, 20, and 23, Wilms discloses a foot treatment device comprising a first fastening portion in the region of the big toe (20), a second fastening portion in a region of the central foot (27), and a hinged flexible splint extending along the inner foot for correction toe joint articulation (11, 25, 16). The device consists of two hinged splint shanks (11, 25) with a lenticular cross-section adapted to the shape of a human foot that pivot about an articulated hinge (16) with an axis corresponding approximately to the joint axis of the main big toe (Figure 1).

Regarding claim 17, Wilms further discloses a foot spreading pad (32) on the area of the sole of the foot behind the main joints of the toes (Figure 1).

Regarding claim 21, both hinged splint shanks have a free end and an end at the hinge (Figure 1).

Regarding claim 24, the hinge ends of the hinged splint shanks rotate with a rotational symmetry about a pivot axis corresponding approximately to that of the big toe.

Regarding claim 25, Wilms discloses that the shanks are made of a spring metal (page 1, lines 65-70).

Regarding claim 26, a force can be exerted on the big toe in the direction on the inner side of the foot for lateral correction (page 2, lines 15-30).

Regarding claims 29 and 31, the shanks have a three-dimensional form substantially that of a plate with first and second longitudinal boundaries and a narrow boundary (Figure 1) adapted to the anatomical features of a human foot.

Regarding claim 30, Wilms discloses one or more slots (28) in the region of the longitudinal boundary with edges parallel to the longitudinal boundary which form a central stay, and edge stay, and intermediate stays (Figure 1).

Regarding claim 37, the surfaces of the shanks that lie along the users foot are smooth (Figures 3 and 4).

Regarding claim 49, the annular bindings around the central foot and toe are positioned without creating steps (Figure 3).

Regarding claim 51, the device is not fixed rigidly to the foot and allows at least some movement for adapting the position of the hinge axis of the hinge mechanism to the anatomical features of the users foot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms.

Regarding claim 48, Wilms discloses spring metal for forming the shanks, but lacks a plastic shank. However, the feature of choosing a plastic shank instead of a metal shank is

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considered an obvious design choice since it appears that Wilms flexible metal shank would perform equally well with the plastic shank. for allowing the slight bending on the hinge shanks for correction the toe alignment. Furthermore, the feature of choosing a particular plastic material (i.e., polycarbonate) is considered an obvious design choice since polycarbonate is a well known material in the art. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 50, Wilms is silent as to when the annular bindings are threaded to the second hinge shank. However, claim 50 adds no further structural limitation to the claims and it appears to be a matter of personal preference as to the binding (27) being threaded to the second hinged splint shank prior to application to the patient's foot, so long as the patient is able to slide the foot into the formed loop from the strap and shank.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms as applied to claims 1, 3-5, 15, 17, 20, 21, 23-26, 29-31, 37, 49, and 51 above and further in view of Scholl (US 1,055,810). Wilms is silent as to a tension element for exerting a force on one or more neighboring toes. Scholl discloses a similar toe straightening device with a tensioning element for exerting a force on a neighboring toe (column 2, lines 60-65 and 85-95). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wilms device with a tensioning element as taught by Scholl for applying a force to a neighboring toe in order to straighten the second-toe, which is often distorted by the misalignment of the big toe as well.

Claims 22, 34-36, and 38-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms as applied to claims 1, 3-5, 15, 17, 20, 21, 23-26, 29-31, 37, 49, and 51 above and further in view of Tyrell (US 6,254,559).

Regarding claims 34, 35, 40, 41, 42, 45, and 46, Wilms does not disclose an annular hinge, but rather a rivet hinge with a flexible material that produces the same force on the toe. Tyrell discloses an annular hinge with a hinge disk (19, 18) and a hinge ring (12) joined as one piece with a hinge splint shank for use on a hip joint that fixes a flexion extension plane by angles (20, 25) with the pivot axis for correct alignment of the joint members. Cap plate (15) is fixed to the splint shanks by screws (16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the rivet hinge of Wilms with an annular hinge as taught by Tyrell for providing more controlled angular correction of the big toe joint.

Regarding claim 22, as best understood by the examiner, the ends near the hinge joint have a three dimensional form similar to a ball joint for allowing rotation (i.e., as the person walks, sits, etc.) and for allowing rotation about the pivot axis (i.e., for setting the flexion extension angle). The ends are formed such that the hinge ends can be inserted into each other and interlock (Figure 5).

Regarding claim 36, the modified device of Wilms and Tyrell is silent as to the material thickness of the hinged splint shanks. Absent a critical teaching and/or showing of unexpected results derived from providing a material thickness that tapers towards the edge regions of the shanks, the examiner contends that the material thickness is an obvious design choice that does

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not patentably distinguish applicant's invention. Furthermore, it appears as though the modified device would perform equally well with the tapered material thickness claimed by the Applicant.

Regarding claim 38, Tyrell discloses an annular ridge (Figure 2 - i.e., indents in 18, 19 or 17). Tyrell is silent as to the ridge being moulded onto the hinge disk. However, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)(citations omitted).

Regarding claim 39, the axial positioning on the hinge ring relative to the hinge disk operates together with a step (17).

Regarding claims 43 and 44, Tyrell discloses that the angle is approximately 20 degrees to the vertical (column 3, lines 10-15), which would produce an angle between 75-115 degrees and 70-110 degrees for α and β depending on how the angles were defined.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ford, Levitt, and Mayer are cited to show other toe straightening devices.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270.

The examiner can normally be reached on Monday - Friday 9-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kristen C. Matter
Examiner
Art Unit 3771


JUSTINE R. YU
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6/7/07